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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED: 3

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/491,910

Applicant(s)

Piper

Examiner

Melissa Kimball

Group Art Unit

1638



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-32 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-32 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-32 are pending.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10, 14, 18, 23, 27, and 31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to "maize plant breeding program"s. A breeding program comprises more than the plants involved; it additionally comprises the ideas behind each choice of cross or self-pollination and the ideas behind each selection step. The claims should be amended to read directly on the methods of the breeding program which are practical applications of these ideas (MPEP 2106).

Claim Rejections - 35 USC § 112

2. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ the novel hybrid maize seed designated '38J54'. Since the hybrid maize seed is essential to the claimed invention it must be either known and readily

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available to the public or can be made or isolated without undue experimentation. If the hybrid maize seed is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the exact hybrid maize seed designated '38J54' and it is not apparent if the seed is known and readily available to the public. Thus, a perfected deposit may be used for enablement purposes. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

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- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

For each deposit made pursuant to these regulations, the specification shall be amended to contain (see M.P.E.P. § 1.809):

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and,
- (4) The name and address of the depository.

3. Claims 1-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5 and 7 are indefinite in the recitation of "ATCC accession No. ____". The designation of the instant hybrid maize line "38J54" is arbitrary and creates ambiguity in the claims. For example, the plant disclosed in this application could be designated by some other

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arbitrary name or the assignment of the name "38J54" could be arbitrarily changed to designate another seed or plant. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970). Dependent claims are included in this rejection because they each fail to correct the deficiency of the claim from which they ultimately depend.

4. Claims 12-15 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation of "genetic material of said plant contains one or more transgenes" in claims 12 and 25 fails to set the metes and bounds of the invention, as the term does not carry with it any limitation as to the structural or physical properties of the DNA. The insertion of DNA via an abiotic or biotic method of genetic transformation would produce an organism which would be indistinguishable from its parents unless the DNA was that not found in said plant or was distinguishable from said parents' DNA. That is, the person having skill in the art could insert an additional copy of the rDNA gene from maize, or any other gene from maize, into the selected maize line. While the specification provides a narrative of the transgene within the scope of the claim, the claimed invention is not limited by the instant recitation to those specific embodiments. Dependent claims 13-15 and 26-28 fail to correct the deficiency of the claim from which they

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ultimately depend. Accordingly, the claims fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention

5. Claims 11, 15, 19, 24, 28 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because they are drawn to plants "wherein at least one ancestor" is the instant maize plant 38J54 and "expressing a combination of at least two 38J54 traits" from a Markush group of traits. It is unclear how one of skill in the art would determine whether or not a plant with "good grain quality", "good agronomics" and/or "good stability over a wide range of environments", for example, expresses the traits due to inheritance of genomic material from 38J54 or simply happens to express similar traits. The traits of the instant hybrid maize plant are not necessarily encoded by a single gene and it is unclear how they would be distinguished as "38J54 traits". As claimed, the traits are not necessarily inherited from 38J54; the traits could arise in 38J54-derived lines from the genetic material inherited from other parents in their ancestry and just happen to be phenotypically similar to the traits of the 38J54 line. The claims have no limitation on the degree of relatedness of the derived plant and broadly reads on plants that are vastly different from the plant taught in the specification. As claimed it is unclear how much of the 38J54 genome would be imparted to the offspring derived from 38J54 because it is not explicitly stated how many breeding cycles would use the deposited maize line, its progeny, or regenerants

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from tissue culture. A skilled plant breeder would be unable to determine the metes and bounds of the claims.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 15, 19, 24, 28 and 32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carrigan.

Claims are directed to maize plants having '38J54' as an ancestor and expressing two or more '38J54' traits.

Carrigan teaches a maize plant with more than two '38J54' traits. The maize plant '38D66' comprises the following phenotypic traits: relative maturity of 91, excellent brittle snap resistance and suited to the Northcentral US (col. 11).

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Carrigan does not teach the cultivar '38J54' however one of skill in the art would be unable to distinguish the plants encompassed by the instant claims from the prior art cultivar because, as claimed, the plants have no specific genotype which would distinguish them from plants known in the prior art and because each of the claimed traits is known in the prior art.

No claim is allowed.

GENERAL INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Kimball whose telephone number is (703) 305-6999. The examiner can normally be reached on weekdays from 9:30 am to 7 pm.

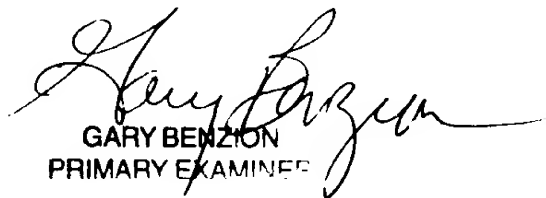
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MLK

March 26, 2001


GARY BENZION
PRIMARY EXAMINER